IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: *Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC v. Warner Chilcott Public Limited Company, Warner Chilcott Company , Inc., Warner Chilcott Company LLC, Warner Chilcott (US), LLC, Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott Sales (US) LLC, Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Lupin Ltd., and Lupin Inc.*, Civil Action No. 14-cv-102-S-PAS (D.R.I.)	Civil Action No. 1:13-md-2472-S-PAS JURY TRIAL DEMANDED

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC bring this civil action against Defendants Warner Chilcott Public Limited Company, Warner Chilcott Company, Inc., Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, Warner Chilcott Laboratories Ireland, Limited, Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott Sales (US), LLC (collectively, "Warner Chilcott"), Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson"), Lupin Ltd., and Lupin Inc. (collectively "Lupin") (Watson and Lupin are collectively referred to as "Generic Defendants," and all Defendants are collectively referred

to as "Defendants"), under the antitrust laws of the United States. For their Amended Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful exclusion of competition from the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (each containing 1 mg of norethindrone acetate and 20 µg [microgram, mcg or µg] ethinyl estradiol) and 4 ferrous fumarate tablets (placebo), which Warner Chilcott sold under the brand-name Loestrin 24 Fe ("Loestrin 24" or "Loestrin 24 Fe"). As alleged below, Warner Chilcott, both on its own and in concert with the Generic Defendants, engaged in an overall scheme to improperly maintain and extend Warner Chilcott's monopoly power in the market for Loestrin 24 Fe and its generic equivalents, to the detriment of Plaintiffs, causing them to pay overcharges for Loestrin 24 FE. That scheme included reverse-payment agreements whereby Warner Chilcott made substantial payments first to Watson and then to Lupin to delay the launch of their generic versions of Loestrin 24 Fe.

2. Loestrin-based oral contraceptive products have been sold in the United States since 1973. The basic method of using a combination preparation of norethindrone acetate and ethinyl estradiol pills, followed by placebo pills, to prevent pregnancy has been known for decades. Despite full knowledge of those facts, Warner Chilcott continued to seek and obtain new patents on minor variations of those basic ingredients and methods of use. Warner Chilcott armed its massive sales force with disclosures of its questionable patents to serially encourage doctors to write prescriptions for the latest "patented" version of Loestrin. Warner Chilcott knew that its various formulation patents were weak and subject to defeat by generic manufacturers as invalid, unenforceable, and not infringed. For this reason, Warner Chilcott serially compensated

the Generic Defendants as a *quid pro quo* to induce the Generic Defendants to drop patent challenges that Warner Chilcott knew it could not defeat.

3. Warner Chilcott only had one patent with claims that allegedly covered Loestrin 24 Fe: U.S. Patent No. 5,552,394 (the "'394 Patent"). The '394 Patent did not claim any drug compound or drug formulation. Instead, the '394 Patent covered only a method of using certain drug compounds and formulations that are not patented—specifically, adding three extra days of active tablets to the patient's dosing regimen. Warner Chilcott did not apply for the '394 Patent and was not the inventor of the alleged invention claimed in the '394 Patent. The application that matured into the '394 Patent was filed on July 22, 1994, and the patent issued on September 3, 1996 to Eastern Virginia Medical School ("EVMS"), formerly known as the Medical College of Hampton Roads. A doctor in Virginia employed by EVMS, Gary D. Hodgen, applied for the '394 Patent and was listed as the only inventor of the '394 Patent. Warner Chilcott ultimately purchased the '394 Patent after it had changed ownership several times. The Generic Defendants each sent Warner Chilcott detailed letters putting Warner Chilcott on notice that the '394 Patent it purchased was invalid.

4. When faced with the prospect of imminent generic competition to Loestrin 24 Fe, Warner Chilcott paid Generic Defendants Watson and Lupin to withdraw their challenges to the '394 Patent and delay their entry into the market. Warner Chilcott then used the purchased delay to switch as many Loestrin 24 prescriptions as possible to a chemically and pharmaceutically identical drug called Minastrin 24 Fe, which Warner Chilcott believed might not face generic competition for several years.

5. Warner Chilcott sued each of the Generic Defendants for patent infringement after each of the Generic Defendants submitted applications to the United States Food and Drug Administration ("FDA") for approval of their generic Loestrin 24 products, asserting that the

Generic Defendants' products infringed Warner Chilcott's '394 Patent. Warner Chilcott subsequently sued Mylan Inc., Mylan Pharmaceuticals, Inc., and Famy Care Ltd. (collectively, "Mylan") for patent infringement after Mylan submitted an application to the FDA for approval to sell a generic version of Loestrin 24. Warner Chilcott filed these patent lawsuits without regard to whether or not they had legal merit. Its purpose in filing the lawsuits was not to win them, but to use them to delay the onset of generic competition. Under the applicable provisions of the Hatch-Waxman Amendments of the Federal Food, Drug and Cosmetic Act (discussed in detail below), the mere filing of these lawsuits prevented the FDA from approving the generic drug for 30 months, regardless of the merits of the lawsuit. To automatically obtain 30 months of delay, Warner Chilcott did not have to win the patent cases; it only had to file them.

6. Warner Chilcott's lawsuits asserting the '394 Patent were objectively baseless and filed solely as an anticompetitive weapon against the Generic Defendants with the intent of illegally extending Warner Chilcott's monopoly by delaying the entry of generic versions of Loestrin 24 into the market.

7. Warner Chilcott knew that the '394 Patent would not prevent generic competition because Warner Chilcott could not get preliminary injunctions based on the patent and was very likely to lose the patent cases if they were litigated to conclusion. Therefore, on January 9, 2009, as the 30-month stay against the first potential generic competitor (Defendant Watson) was nearing expiration, Warner Chilcott paid Watson to withdraw its challenge to the patent and delay its entry into the market. In exchange for substantial payments from Warner Chilcott, representing a share of the monopoly profits that the lack of generic competition made possible, Watson agreed to stay out of the market until January 2014—just six months before the '394 Patent expired.

8. Warner Chilcott then repeated this ploy with the second potential generic competitor, Defendant Lupin. As was the case with Watson, the '394 Patent could not prevent competition from Lupin because Warner Chilcott was very likely to lose the patent case against Lupin if it were litigated to conclusion. Accordingly, Warner Chilcott again agreed to share some of the monopoly profits with its potential competitor. In exchange for substantial payments from Warner Chilcott, Lupin agreed to withdraw its challenge to the patent and delay its entry until July 2014—the very end of the patent term.

9. Warner Chilcott also asserted the '394 Patent in a third objectively baseless lawsuit against Mylan when it sought to market a generic version of Loestrin 24. In that objectively baseless lawsuit, Warner Chilcott again obtained a 30-month stay simply by filing the case. The '394 Patent could not prevent competition from Mylan because Warner Chilcott knew it would very likely lose the patent case if it were litigated to conclusion, so it settled with Mylan.

10. Having purchased the delay of generic competition, Warner Chilcott used that time to impair the effectiveness of generic competition once it started in January 2014. Warner Chilcott employed what is known as a "product hop," whereby it converted prescriptions for Loestrin 24 Fe, which was to face generic competition beginning in January 2014, to a follow-on branded product that may have enjoyed patent protection for a longer period of time. The follow-on product was called Minastrin 24 Fe ("Minastrin 24"). . Minastrin 24 is chemically identical to and follows the same dosing regimen as Loestrin 24. The only differences between the two products are that Warner Chilcott added flavoring to the *inactive* pills dispensed with a prescription for Minastrin 24 and included in the Minastrin 24 label an instruction to patients to chew and swallow the pills. Loestrin 24 pills were already chewable. However, the addition of flavoring to the inactive pills and the change in labeling meant that a pharmacist could not fill a

prescription for Minastrin 24 with a generic version of Loestrin 24, notwithstanding the physical identity of the active pills. Thus, by switching the market from Loestrin 24 to Minastrin 24, Warner Chilcott effectively eliminated the market for generic Loestrin 24.

11. Minastrin 24 provides no medical, convenience, or other benefits to patients as compared to Loestrin 24. Instead, best medical practice is not to switch a woman to a new type of oral contraceptive if she is doing well on an existing regimen. Moreover, studies have shown that women have no interest in chewing birth control pills. Nevertheless, beginning in August 2013, Warner Chilcott abruptly discontinued Loestrin 24 and instructed its army of sales representatives to urge doctors to stop writing prescriptions for Loestrin 24 and start writing them for Minastrin 24.

12. Absent the unlawful payments from Warner Chilcott to Watson and Lupin to delay the launch of their generic versions of Loestrin 24, Warner Chilcott would never have launched Minastrin 24. Alternatively, even if Warner Chilcott had launched Minastrin 24 absent the payments for delay, it would have made very few sales. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. Minastrin 24 offers no such benefits. Warner Chilcott's ploy of switching prescriptions to Minastrin 24 depended on launching those drugs before generic versions of Loestrin 24 were available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the FDA approved Minastrin 24 for sale. Consequently, Warner Chilcott would not have launched that product or, if it had, it would have made few sales.

13. But for the anticompetitive scheme and agreements alleged herein, a generic version of Loestrin 24 would have been available to Plaintiffs in the United States as early as

September 2009, when the FDA granted final approval to Watson's generic Loestrin 24 Fe. Other generic versions of Loestrin 24, including an authorized generic version marketed directly or indirectly by Warner Chilcott, would have subsequently entered the market, driving down generic prices to close to marginal cost. Plaintiffs (and/or their assignors) would have purchased those generic products. Moreover, absent the anticompetitive scheme and agreements alleged herein, Warner Chilcott would not have been able to substantially reduce the number of Loestrin 24 Fe prescriptions available for AB-rated generic substitution.

14. Warner Chilcott's sham lawsuits seeking to enforce the '394 Patent and Defendants' unlawful scheme and agreements were designed to and did in fact: (a) delay the entry of less expensive generic oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets in the United States; (b) fix, raise, maintain or stabilize the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets products; and (c) allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets market to Warner Chilcott.

15. Plaintiffs seek a judgment that Defendants' anticompetitive scheme and agreements, as further described below, are unlawful under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and awarding Plaintiffs treble damages and other relief under section 4 of the Clayton Act, 15 U.S.C. § 15(a).

16. Plaintiffs are direct purchasers or assignees of direct purchasers of Loestrin 24 Fe and are included in the proposed class definition in actions currently pending in this Court as part of *In re Loestrin 24 Fe Antitrust Litigation*, MDL Docket No. 2472. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first such class action on May 14, 2013. Plaintiffs suffered no injury from Defendants' anticompetitive scheme until

September 1, 2009, when generic entry would have occurred but for the unlawful conduct alleged below, and the claims asserted in this action therefore accrued no earlier than September 1, 2009. September 1, 2009 to May 14, 2013 is less than the applicable four-year limitations period.

II. THE PARTIES

17. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Loestrin 24, to the public. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal") and AmerisourceBergen Drug Corporation, two pharmaceutical wholesalers, which during the relevant period purchased Loestrin 24 directly from Warner Chilcott for resale to Walgreen and which have assigned their claims arising out of those purchases to Walgreen.

18. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Loestrin 24, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Loestrin 24 directly from Warner Chilcott for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

19. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs, including Loestrin 24, to the public. Safeway brings this action in its own behalf and as the assignee of Cardinal and McKesson Corporation ("McKesson"), another pharmaceutical wholesaler, which during the relevant period purchased Loestrin 24 directly from Warner Chilcott for resale to

Safeway and which have assigned all or a portion of their claims arising out of those purchases to Safeway.

20. Plaintiff HEB Grocery Company L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores in several states at which it dispenses prescription drugs, including Loestrin 24, to the public. HEB brings this action in its own behalf and as the assignee of Cardinal and McKesson, which during the relevant period purchased Loestrin 24 directly from Warner Chilcott for resale to HEB and which have assigned their claims arising out of those purchases to HEB.

21. Plaintiff Albertson's LLC ("Albertson's") is a Delaware limited liability company having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertson's owns and operates retail stores in several states at which it dispenses prescription drugs, including Loestrin 24, to the public. In 2013, Albertson's purchased and now owns a substantial number of pharmacies previously owned by Supervalu Inc. Albertson's brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Loestrin 24 directly from Warner Chilcott for resale to Supervalu Inc. McKesson has assigned a portion of its claims arising out of those purchases to Supervalu, and Supervalu (with McKesson's consent) has re-assigned those claims to Albertson's.

22. Defendant Warner Chilcott Public Limited Company is a company organized and existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland L2 00000.

23. Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. This Defendant holds

an approved New Drug Application from the FDA for a formulation of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets, which it sells throughout the United States under the brand name Loestrin 24 Fe. This Defendant is a wholly owned subsidiary of Warner Chilcott PLC.

24. Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

25. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized and existing under and the laws of Bermuda, having its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866.

26. Defendant Warner Chilcott Laboratories Ireland Limited is a company organized and existing under the laws of the Republic of Ireland, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

27. Defendant Warner Chilcott Company, Inc., is a company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

28. Defendant Warner Chilcott Sales (US), LLC is a Delaware limited liability company with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

29. Defendant Warner Chilcott Corporation is a Delaware corporation with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

30. The foregoing Defendants are collectively referred to herein as "Warner Chilcott." Warner Chilcott is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district. On October 1, 2013, Warner Chilcott

was acquired by Defendant Actavis, Inc. Actavis, Inc. was required to divest certain assets, including generic Loestrin 24 Fe, in order to obtain regulatory approval of the acquisition.

31. Defendant Actavis, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054.

32. Defendant Watson Pharmaceuticals, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

33. Defendant Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

34. Defendants Actavis, Inc., Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as "Watson." Watson is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

35. Defendant Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

36. Defendant Lupin Pharmaceuticals Inc. is a corporation organized and existing under the laws of Virginia, having its principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals Inc. is a wholly-owned subsidiary of Lupin Ltd.

37. Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc. are collectively referred to herein as "Lupin." Lupin is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

38. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

39. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for Loestrin 24 Fe and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

40. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c) and 28 U.S.C. § 1407(a).

IV. OPERATIVE FACTS

A. Characteristics of the Prescription Pharmaceutical Marketplace

41. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition.

Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

42. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Loestrin 24, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) must pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

43. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

44. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to increase price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost

is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

45. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

46. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer must subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

47. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

48. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness in the brand manufacturer's original NDA. An ANDA must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

49. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

50. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

51. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

52. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

53. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its

product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

54. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 20% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

55. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation,

by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

56. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

57. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

58. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final

decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

59. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers can subvert the failure-to-market provision and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

60. In addition, brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where it is likely that the generic forfeited that exclusivity under one of the applicable MMA forfeiture provisions, e.g., the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. This results in a windfall to the generic and a subversion of the regulatory scheme. Because the FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain *de facto* exclusivity—even where it should be forfeited *de jure* under the MMA—dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that

would trigger the start of the 180-day period. Subsequent filers have less incentive to litigate to judgment when most of the benefits of a litigation win would go to the first filer.

E. The Benefits of Generic Drugs

61. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 20% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Warner Chilcott as a grave threat to their bottom lines.

62. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

63. Generic competition enables Plaintiffs to purchase generic versions of a brand-name drug at substantially lower prices.

64. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements at issue here.

F. The Impact of Authorized Generics

65. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product by the brand manufacturer or a licensed third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues.

66. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Authorized Generic Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by 52% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

67. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as

Plaintiffs benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

68. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

69. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and given the absence of any other form of price competition from the brand manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

V. DEFENDANTS' ANTICOMPETITIVE SCHEME

A. Warner Chilcott's Enforcement of a Fraudulently Procured Patent.

70. Traditional oral contraceptives contain 21 active tablets and 7 placebo tablets. Loestrin 24 contains 24 active tablets (containing 1 mg of norethindrone acetate and 20 µg of ethinyl estradiol) and 4 placebo tablets (containing ferrous fumarate). Warner Chilcott marketed Loestrin 24's longer, 24-day active tablet regimen as providing an effective low dose birth control associated with shorter, lighter periods with less bleeding. Other oral contraceptives are

not AB-rated to Loestrin 24, cannot be automatically substituted for Loestrin 24 by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Loestrin 24, and thus are not economic substitutes for, or reasonably interchangeable with, Loestrin 24.

71. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

72. In connection with its Loestrin 24 NDA, Warner Chilcott listed the '394 Patent in the Orange Book as the only patent covering Loestrin 24 or a method of using Loestrin 24. The purported invention described in the '394 Patent is a method of female contraception which is characterized by a reduced incidence of breakthrough bleeding that comprises administering the claimed combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle. Loestrin 24 is the purported commercial embodiment of the '394 Patent.

73. When Warner Chilcott listed the '394 Patent in the Orange Book as the only patent standing in the way of generic versions of Loestrin 24, individuals at Warner Chilcott, including without limitation Warner Chilcott's then-CEO, Roger M. Boissonneault, knew that the '394 Patent was invalid or unenforceable, as described more fully below.

74. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. In fact, norethindrone and ethinyl estradiol have served as the active ingredients in oral contraceptives dating back to at least the early 1970s. For example, Warner Chilcott's Loestrin Fe 1/20 product—which contains tablets identical to those used in Loestrin 24 Fe—was approved by the FDA on April 30, 1973. The only difference between the '394 Patent (and the corresponding Loestrin 24 product) and Loestrin Fe 1/20—which has been on the market for close to forty years—is that the '394 Patent

claims require 23-25 days of tablets whereas the Loestrin 1/20 product is packaged in units of 21 active tablets.

75. Because the '394 Patent claims only a narrow method of using active ingredients that have been used for decades as an oral contraceptive to prevent pregnancy, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 before the expiration of the '394 Patent. The generic manufacturers believed that they could obtain a court ruling that the '394 Patent was invalid and/or unenforceable.

76. The sole inventor of the '394 Patent was Dr. Gary D. Hodgen. Hodgen filed the application that became the '394 Patent on July 22, 1994. He assigned the application to his employer, Eastern Virginia Medical School ("EVMS," formerly The Medical College of Hampton Roads), on September 26, 1994. On October 2, 1994, EVMS assigned the application that became the '394 Patent to Warner-Lambert Company LLC (for its Parke-Davis division). Warner-Lambert assigned the '394 Patent to Galen Holdings, PLC in March 2003. In July 2004, Galen Holdings PLC changed its name to Warner Chilcott PLC, and on August 1, 2004, that entity assigned the '394 Patent to Warner Chilcott Company, Inc.

77. Prior to filing the application that issued as the '394 Patent, beginning as early as January 1993, scientists at EVMS conducted a clinical study in which study participants took tablets of the oral contraceptive Loestrin 1/20 for 25 consecutive days of the 28-day cycle (the "1993 Study"). The participants in the clinical study were under no confidentiality restrictions about the method used in the study. Like Loestrin 24, each Loestrin 1/20 tablet contained l mg of norethindrone acetate and 20 µg ethinyl estradiol. During the time of the clinical trial in 1993, Loestrin 1/20 was commercially marketed in the United States by Parke-Davis (a division of Warner-Lambert).

78. Warner Chilcott's then-CEO, President and Director, Roger Boissonneault, was aware of Hodgen's work on the '394 Patent from at least 1993. He was instrumental in acquiring the '394 Patent for two different companies—first when he acquired the pending application for the patent while at Parke-Davis, and again when he acquired the issued patent from his prior company once he joined Warner Chilcott. In 1993, Hodgen wrote a letter to Boissonneault (who at the time was Vice President of Female Healthcare at Parke-Davis), explaining why Hodgen thought that Parke-Davis should pay EVMS for the "technology" used in the clinical study. Hodgen's letter apparently persuaded Boissonneault, because on October 2, 1994, EVMS assigned ownership of the application that became the '394 Patent to Boissonneault's then-employer, Warner-Lambert (the corporate parent of Parke-Davis). In September 2000, Boissonneault was appointed Chief Executive Officer and Director of Warner Chilcott's predecessor, and in March 2003, Warner-Lambert assigned the '394 Patent to that predecessor which is known today as Warner Chilcott. Boissonneault was Chief Executive Officer, President and Director of Warner Chilcott until 2013.

79. While Hodgen was working on the 25-day Loestrin 1/20 clinical study in 1993, and while he was prosecuting the application for the patent, Hodgen was aware that other companies were investigating an extended regimen method of use for oral contraceptives utilizing 23-25 hormone-containing tablets in a 28-day cycle. In particular, Hodgen was aware that the German pharmaceutical company Schering AG was investigating such extended regimen oral contraceptives based on a conference he attended. As a result, Hodgen sought to patent the method of use in the 1993 EVMS Loestrin 1/20 clinical study before any other individuals investigating the same method of use. To this end, on July 22, 1994, Hodgen filed the patent application that issued as the '394 Patent.

80. In pursuit of a patent on the method of use in the 1993 EVMS Loestrin 1/20 clinical study, Hodgen and Parke-Davis (the "Applicants") knowingly defrauded the United States Patent & Trademark Office (the "PTO") through a series of acts and omissions, including: concealing from the PTO the prior invalidating public use of the claimed method during the EVMS clinical study; making false statements to the examiner during prosecution of the application; and intentionally withholding material prior art from the PTO. As set forth in more detail in the paragraphs below, but for the Applicants' knowingly fraudulent acts and omissions, the PTO would have never issued the '394 Patent. When Warner Chilcott enforced the '394 Patent against generic ANDA filers, it knew the patent had been fraudulently obtained because senior Warner Chilcott executives—including Boissonneault—had been executives at Warner-Lambert when Warner-Lambert acquired and prosecuted the application that resulted in the '394 patent from October 1994 until the patent issued on September 3, 1996. On March 3, 2003, at the time Warner Chilcott acquired the '394 Patent, it issued a press release admitting that Boissonneault and other former Warner-Lambert executives had been involved with the development of Loestrin 24 during their prior employment at Warner-Lambert.

81. In 1993, Loestrin 1/20 was commercially marketed by Parke-Davis of Morris Plains, New Jersey. The participants in the 1993 Study knew they were taking Loestrin 1/20 tablets for 25 consecutive days of the 28-day cycle. The participants in the 1993 Study were under no confidentiality restrictions about the method used in the study. The '394 Patent Applicants, including Hodgen and Parke-Davis's Boissonneault, knew about the study. The Applicants intended to conceal the 1993 Study from the PTO. The 1993 Study is an invalidating prior public use of one or more claims of the '394 Patent, and the Applicants had a duty to disclose the 1993 Study to the PTO. But the Applicants did not disclose it to the PTO during the prosecution of the '394 Patent, and intended to deceive the PTO by concealing the 1993 Study.

Warner Chilcott knew that this invalidating prior use had not been disclosed to the PTO when it enforced the '394 Patent against Loestrin 24 ANDA filers.

82. The Applicants also intentionally made false statements and withheld material information from the PTO concerning the amount of estrogen in prior art oral contraceptives. The Applicants, including Hodgen, knew about commercially available oral contraceptives containing 20 µg of ethinyl estradiol ("EE"). However, in response to an Office Action, a notification to the applicant regarding problems with the application, the Applicants stated to the PTO that all commercially available combination formulations in the United States contained a minimum of 30 µg of EE and exposed women to higher annual estrogen amounts than the claimed regimen. The Applicants' statement to the PTO was materially false and intended to deceive the PTO. Warner Chilcott knew that these false statements and material omissions had been made during prosecution of the '394 Patent when it enforced the '394 Patent against Loestrin 24 ANDA filers.

83. Specifically, in response to a January 23, 1995 PTO Office Action, the Applicants stated to the PTO that all commercially available oral contraceptive combination formulations "contain at least 30 mcg of EE," where "mcg" is synonymous with "µg." The Applicants wrote to the PTO on July 19, 1995 stating: "[T]he claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 µg EE (Craft uses 50 µg) and a regimen of 21 dosing days plus a 7-day pill free interval." However, by at least 1992, the Applicants knew of commercially available oral contraceptives containing less than 30 µg of EE. In particular, by 1992, the Applicants knew that Loestrin 1/20 tablets contained 20 µg of EE and were commercially available in the United States. For example, beginning as early as 1992, Hodgen and others conducted a preclinical study involving

monkeys. The oral contraceptive given to the primates consisted of Loestrin 1/20 tablets that were adjusted to fit the smaller body weight of the primates. According to an internal report, Dr. Hodgen stated that the "in-house reformulation was achieved by grinding to powder a commercially available monophasic pill (Loestrin 1/20, Parke-Davis, Morris, NJ), which originally contained 1 mg of norethindrone acetate and 20 µg of ethinyl estradiol per tablet in a conventional 21-day pack, along with 7 iron containing placebos."

84. Because Hodgen used Loestrin 1/20 tablets in this study, he knew about Loestrin 1/20 tablets as early as 1992. Hodgen also knew that the 1993 Study used "commercial blister packs" of Loestrin 1/20. The annual exposure to estrogen from the Loestrin 1/20 regimen taken for 21 days of a 28-day cycle is just over 5.5 mg. However, the dosing regimen claimed in the '394 Patent included up to 35 µg of EE for up to 25 consecutive days of the 28-day cycle. Over a period of one year, women following the claimed regimen could be exposed to more than 11.4 mg of estrogen. Accordingly, the statement of the '394 Patent Applicants in their July 19, 1995 response to a PTO Office Action that all combination formulations commercially available in this country contain at least 30 µg EE was a knowingly false statement.

85. Moreover, during the prosecution of the '394 Patent, the PTO expressly found the amount of estrogen in prior art formulations of oral contraceptives to be material to the patentability of the '394 Patent. Following the Applicants' July 19, 1995 response, on November 28, 1995, the PTO issued a final rejection of the pending claims based on the Craft and Upton references. In the PTO's final rejection, the PTO stated that the difference between the estrogen amount claimed in the '394 Patent and disclosed by the prior art was not patentable. The PTO wrote: "Claim 1 recites a possible dosage of 35 mcg of estrogen which is only 15 mcg lower than the 50 mcg dosage taught by Craft et al. It has not been demonstrated that a dosage regimen differing by only 15 mcg less of estrogen has unexpected contraceptive and reduced

breakthrough bleeding results." Thus, the PTO expressly found that the Craft disclosure of 50 µg of estrogen rendered the claims of the application leading to the '394 Patent obvious. The Applicants' statement in the July 19, 1995 response that all combination formulations commercially available in this country contain at least 30 µg EE was a materially false statement. The Applicants intended to defraud the PTO by falsely stating that all U.S. oral contraceptives contain at least 30 µg of estrogen. Warner Chilcott knew that these statements made during patent prosecution were materially false when it enforced the '394 Patent against Loestrin 24 ANDA filers.

86. The Applicants knew that a commercially available oral conceptive in the United States, *i.e.*, Loestrin 1/20, exposed women to half as much estrogen as claimed in the '394 Patent. Thus, the Applicants' statement in their July 19, 1995 response that the claimed regimen leaves the patient with a total estrogen exposure per annum below all other oral contraceptives commercially available in this country was false. The total annual dose of estrogen in the known prior art was inconsistent with what the Applicants represented to the PTO during prosecution of the '394 Patent.

87. The Applicants intended to defraud the PTO by falsely stating that the regimen claimed in the '394 Patent reduced the annual estrogen exposure compared to "all other combination formulations commercially available in this country."

88. In addition, the Applicants intentionally concealed a prior art publication that taught one skilled in the art to increase a 21-day schedule of commercial oral contraceptives to 23 days. A 1985 article entitled '"Missed pill' conception: fact or fiction?" observes that the likelihood of conception by a woman using oral contraceptives who misses a pill can be diminished by reducing the pill-free interval for a 28-day cycle. Molloy et al, '"Missed pill' conception: fact or fiction?", Br. Med. J. 1985; 290: 1474-5 ("Molloy"). In Molloy, the author

states: “To reduce the risk of missed pill conception a 28-day pack containing 23 pills and 5 blanks could be substituted for the current 21-day pack. This would still permit a withdrawal bleed without the risk of significant follicular development.”

89. Molloy teaches one skilled in the art to increase a 21-day schedule of commercial oral contraceptives to 23 days. Molloy is material to the patentability of the claims of the ‘394 Patent because the claims of the patent extend the 21-day schedule to 23-25 days.

90. The Applicants were aware of the Molloy reference, as shown by a letter Hodgen wrote to Warner-Lambert during December 1990. The Applicants never disclosed Molloy to the PTO during the prosecution of the ‘394 Patent, and intended to deceive the PTO by withholding Molloy from consideration during the examination of the ‘394 Patent claims. Warner Chilcott knew that the Molloy reference had been withheld from the PTO with the intent to deceive the PTO when it enforced the ‘394 Patent against Loestrin 24 ANDA filers.

91. By at least the time Warner Chilcott began to enforce the ‘394 Patent, it knew the ‘394 Patent issued as a result of the Applicants’ fraud on the PTO. Warner Chilcott knew that the Applicants procured the ‘394 Patent fraudulently before it listed the ‘394 Patent in the Orange Book as the only patent covering Loestrin 24, and it also knew that the Applicants procured the ‘394 Patent fraudulently when it asserted the patent in lawsuits filed against Watson, Lupin and Mylan.

B. Improper Listing of the ‘394 Patent in the Orange Book

92. Hatch-Waxman requires each holder of an approved New Drug Application to list in the Orange Book pertinent patents that the NDA holder believes “could reasonably be asserted” against a manufacturer who makes, uses, or sells a generic version of the drug prior to expiration of the listed patents.

93. Warner Chilcott listed the '394 Patent in the Orange Book even though it knew that patent could not reasonably be asserted against generic manufacturers because it knew the patent was procured fraudulently, and also that the patent was invalid and unenforceable.

94. In addition to Warner Chilcott's knowledge that the '394 Patent Applicants committed fraud and inequitable conduct on the PTO, Warner Chilcott (including at least Boissonneault) also knew before it listed the '394 Patent in the Orange Book that it was not valid because it was anticipated and obvious in light of the prior art.

95. Specifically, Warner Chilcott knew that Hodgen was not the first to file a patent application on an issued patent covering a 23-25 day method of using an oral contraceptive. In addition to the Upton reference described above, on December 22, 1993, Schering AG filed a German patent application for a 23-25 day oral contraceptive regimen; and on June 30, 1994, Schering AG filed a United States patent application on a 23-25 day oral contraceptive regimen, which issued as United States Patent No. 5,583,129 on December 10, 1996. The prior art Schering AG patent disclosed the same active ingredients and the same method of use as Warner Chilcott's later-filed '394 Patent, and is invalidating prior art to the '394 Patent.

96. Warner Chilcott became aware of Schering AG's invalidating prior art patents before it listed the '394 Patent in the Orange Book.

97. Warner Chilcott's listing of the '394 Patent was objectively and subjectively baseless because Warner Chilcott did not believe and could not reasonably have believed that the '394 Patent could be asserted against manufacturers of generic versions of Loestrin 24. Warner Chilcott listed the '394 Patent in the Orange Book in order to create an obstacle to generic competition. By listing the patent, Warner Chilcott forced potential generic competitors to file Paragraph IV certifications, which in turn permitted Warner Chilcott to delay FDA approval of their ANDAs by filing patent litigation and triggering a 30-month stay under Hatch-Waxman.

C. Warner Chilcott's Sham Lawsuits Against Generic Manufacturers

1. Watson

98. On or about June 19, 2006, Generic Defendant Watson notified Warner Chilcott that Watson had filed ANDA No. 78-267, seeking to market a generic version of Loestrin 24. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 Patent.

99. On July 28, 2006, Warner Chilcott filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Watson's generic Loestrin 24 product would infringe the '394 Patent.

100. Warner Chilcott filed the patent infringement case against Watson without regard to the merits of the case. Simply by filing the case, Warner Chilcott obtained the automatic exclusion of Watson from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott very likely would have lost.

101. During discovery, Watson uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the '394 Patent; (2) the validity of the '394 Patent; and (3) the strength of Warner Chilcott's infringement allegations.

102. Warner Chilcott repeatedly delayed the Watson litigation. Among the tactics that it used was seeking the disqualification of Watson's litigation counsel. Warner Chilcott's delay tactic was baseless. Warner Chilcott lost its motion to disqualify before the magistrate judge, and then lost its appeal to the district judge. Warner Chilcott was motivated to delay the Watson litigation because Watson was the first ANDA filer seeking to market a generic version of

Loestrin 24. From Warner Chilcott's perspective, delaying the Watson litigation was desirable because it reduced the incentive of other generic drug manufacturers to challenge the '394 Patent.

103. On January 23, 2008, Watson submitted an Amended Answer and Counterclaim asserting that the claims of the '394 Patent were invalid under one or more of 35 U.S.C. §§ 102, 103 and 112. Watson asserted, for example, that the only difference between Loestrin 24 and Warner Chilcott's prior art product Loestrin Fe 1/20—23 to 25 days of active tablets versus 21 days of active tablets—was trivial, particularly given that doctors routinely advised women using oral contraceptives to take more than 21 tablets in a row in order to delay the onset of menses that might otherwise occur at an inconvenient time. According to Watson, the claims of the '394 Patent were invalid because simply extending the regimen of a well-known prior art product by several days, as taught in the literature and practiced by women, was obvious.

104. Watson also alleged in its Counterclaim that the '394 Patent was unenforceable for a number of reasons, including Warner Chilcott's inequitable conduct, common law fraud and unclean hands. Watson alleged, inter alia, that the Applicants for the '394 Patent intentionally: (1) concealed from the PTO an invalidating public use of the claimed invention that occurred more than one year before the application filing date; (2) made false statements and withheld material information; and (3) withheld prior art teaching an extended regimen of oral contraceptives (more than 21 days).

105. For example, prior to the '394 Patent, it was widely known that Loestrin Fe 1/20 was associated with a high incidence of breakthrough bleeding and an unacceptable failure rate, and that those problems could be alleviated by extending the number of days per cycle during which active pills were administered. A person of ordinary skill in the art would have been motivated to administer Loestrin Fe 1/20 for additional days to alleviate the known problems

associated with its administration over 21 days. Accordingly, the '394 Patent was invalid as obvious in view of the prior art.

106. Despite the foregoing, Warner Chilcott filed an objectively and subjectively baseless lawsuit against Watson that it knew it could not win and did not intend to see through to judgment. It filed the lawsuit against Watson only to secure the 30-month stay.

107. To win the litigation and exclude Watson, Warner Chilcott would have had to defeat each of Watson's arguments regarding invalidity and unenforceability and prove that Watson infringed the '394 Patent. Warner Chilcott knew it could not defeat Watson's arguments. Accordingly, instead of defending the '394 Patent from Watson's attacks, Warner Chilcott decided to protect its monopoly by paying Watson to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24.

2. Lupin

108. In or about July 2009, six months after the announcement of the Warner Chilcott/Watson agreement, Lupin notified Warner Chilcott that it had filed ANDA No. 09-1398, seeking to market generic versions of Loestrin 24. Lupin's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 Patent.

109. On or about September 9, 2009, Warner Chilcott sued Lupin for infringement of the '394 Patent in the United States District Court for the District of Delaware (Civil Action No. 0900673). Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 Patent and non-infringement.

110. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained the automatic exclusion of Lupin from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from

generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott very likely would have lost.

111. During discovery, Lupin, like Watson before it, uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the '394 Patent; (2) the validity of its claims; and (3) the strength of Warner Chilcott's infringement allegations.

112. Warner Chilcott knew that the '394 Patent was invalid and unenforceable, and filed the lawsuit against Lupin only to secure the 30-month stay. Ultimately, before the stay expired, Warner Chilcott paid off Lupin to delay its generic entry and prevent any court judgment regarding the '394 patent.

3. Mylan

113. On April 20, 2011, Mylan sent a Paragraph IV notice to Warner Chilcott regarding ANDA No. 20-2742 for generic Loestrin 24 stating that the '394 Patent was invalid, unenforceable, and/or would not be infringed by the product that is the subject of ANDA No. 20-2742.

114. On June 2, 2011, Warner Chilcott sued Mylan alleging infringement of the '394 Patent. Warner Chilcott filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Mylan's generic Loestrin 24 product would infringe the '394 Patent.

115. Warner Chilcott filed the patent infringement case against Mylan without regard to the merits of the case. Simply by filing the case, Warner Chilcott obtained the automatic exclusion of Mylan from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott very likely would have lost.

116. During the litigation, Mylan conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the '394 Patent; (2) the validity of the '394 Patent; and (3) the strength of Warner Chilcott's infringement allegations.

117. Warner Chilcott knew that the '394 Patent was invalid and unenforceable, and filed the lawsuit against Mylan only to secure the 30-month stay.

4. Additional Sham Litigation Against Watson and Lupin to Protect Lo Loestrin

118. On September 1, 2011, Warner Chilcott filed another objectively and subjectively baseless lawsuit against Lupin in the United States District Court for the District of New Jersey asserting the '394 Patent and another patent, seeking to prevent Lupin from entering the market with a generic version of another Warner Chilcott oral contraceptive, Lo Loestrin. On December 14, 2012, the New Jersey court entered an order dismissing the '394 Patent from the Lupin Lo Loestrin litigation based on Warner Chilcott's covenant not to sue Lupin on the '394 Patent for Lo Loestrin.

119. On May 16, 2012, Warner Chilcott filed another objectively and subjectively baseless lawsuit against Watson in the United States District Court for the District of New Jersey asserting the '394 Patent and another patent, seeking to prevent Watson from entering the market with a generic version of Warner Chilcott's Lo Loestrin product. On February 11, 2013, the New Jersey court entered an order dismissing the '394 Patent from the Watson Lo Loestrin litigation based on Warner Chilcott's covenant not to sue Watson on the '394 Patent for Lo Loestrin.

120. Warner Chilcott filed these additional objectively and subjectively baseless lawsuits against Lupin and Watson knowing that it could not win them. Warner Chilcott knew that the '394 Patent was invalid and unenforceable, and for that reason it provided covenants not to sue to Lupin and Watson on the '394 Patent to prevent any judicial determination of the

validity and enforceability of the '394 Patent, the only patent Warner Chilcott asserted to prevent generic entry into the Loestrin 24 market.

D. Warner Chilcott's Reverse Payment Settlements

1. Watson

121. Having obtained the goal of its Watson lawsuit—the 30-month stay—Warner Chilcott decided to end the case. On or about January 9, 2009, just one month before the 30-month stay was to expire, Warner Chilcott and Watson entered into a Reverse Payment Agreement. Pursuant to that Agreement, Warner Chilcott ended the '394 Patent litigation against Watson, and Watson dropped its Counterclaims against Warner Chilcott. At the time of the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

122. As the first filer, Watson was entitled to 180 days of exclusivity under Hatch-Waxman. If Watson had obtained an order finding the patent invalid or unenforceable, other generic manufacturers would have benefitted from that ruling once Watson's first filer exclusivity had expired without incurring the costs of patent litigation.

123. Under the Reverse Payment Agreement, Watson agreed to delay launching its generic Loestrin 24 product until the earliest of: (1) January 22, 2014; (2) 180 days before a date on which Warner Chilcott granted rights to a third party to market a generic version of Loestrin 24 in the United States; or (3) the date on which another generic version of Loestrin 24 entered the market.

124. As the *quid pro quo* for Watson's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24 Fe product, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott would not have agreed to make these payments absent Watson's agreement to delay entry, and Watson would not have agreed to delay entry without the

payments. Warner Chilcott's substantial payments to Watson under the Agreement took at least four forms.

125. First, the Agreement prohibited Warner Chilcott from launching an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. The Agreement also expressly prohibited Warner Chilcott or its affiliates from marketing or supplying, or granting any third party rights to launch, an authorized generic during the 180-day period. Absent the Agreement, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24 and would have done so. Warner Chilcott has marketed authorized generic versions of other of its branded drugs, including its oral contraceptive, Dovonex. This aspect of the Agreement provided substantial compensation to Watson, which could expect to make approximately double the unit sales, at a much higher price, absent an authorized generic in the market. These higher prices come at the expense of Plaintiffs and constitute overcharges over and above the overcharges caused by the multi-year delay in generic entry.

126. Warner Chilcott's agreement not to market an authorized generic is not an "exclusive license." Under an exclusive license, the patent holder transfers all of its rights to the exclusive licensee and retains no right to practice the invention. In this case, Warner Chilcott retained the right to sell Loestrin 24, but effectively agreed to sell it only at the higher branded price and not at the lower generic price. Far from being an exclusive license, a license in which a patent holder agrees to a restraint on price competition with its licensee constitutes *per se* unlawful horizontal price-fixing.

127. The no-authorized generic promise (the "no AG" promise or agreement) was a large unjustified payment to Watson. Plaintiffs conservatively estimate that the no-AG agreement constituted a payment of $41.2 million from Warner Chilcott to Watson. This estimate is based on a comparison of the revenues that Watson would have expected to earn in

light of the no-AG agreement and the revenues Watson would have expected to earn in the absence of the no-AG agreement. The difference is Warner Chilcott's payment to Watson from the "no AG" promise. This amount is estimated using the known dynamics of the pharmaceutical industry and publicly-available information.

128. The generic substitution rate during a first filer's six-month exclusivity period (that is, the percentage of brand sales that would switch to the generic in the first six months after the generic becomes available) is typically about 80%. According to the 2011 FTC Authorized Generic Study, when only one generic is available, the average generic price discount (*i.e.* the percentage below the pre-generic-entry brand price at which the generic sells) during this period is typically 20%. When an AG also enters the market, that price discount increases and the first filer loses a portion of the generic sales to the AG. The FTC Authorized Generic Study found that the entry of an AG reduces a first filer's revenues by 52%. Using these figures—80% generic substitution within six months, 20% price discount with one generic, and 52% reduction of the first filer's revenues with the entry of an AG—the no-AG payment to Watson can be plausibly estimated.

129. As of the time of Defendants' agreement, sales of Loestrin 24 were $247.6 million per year. Half of that amount (sales during Watson's six-month exclusivity period) would be $123.8 million. Using a conservative 80% generic substitution rate and 20% price discount, Watson would earn approximately $79.23 million from generic Loestrin 24 sales during its six-month exclusivity period if no AG were launched. If Warner Chilcott launched an AG, Watson's revenues would decline by 52% or $41.2 million. That $41.2 million decrease in Watson's revenues resulting from the launch of an AG is a rough estimate of the value of Warner Chilcott's no-AG agreement.

130. Warner Chilcott's $41.2 million no-AG payment is far larger than the average total patent litigation costs for a Hatch-Waxman patent case (and even larger still than the costs that likely remained at the time that the Watson case was settled). A recent survey by the Association of Intellectual Property Lawyers of America estimated that the median total cost of patent infringement litigation associated with ANDA filings under the Hatch-Waxman Act was just $6 million. Warner Chilcott and Watson reached their no AG deal more than two years into their patent litigation. Warner Chilcott filed suit in July of 2006 and the settlement agreement was reached in January of 2009. Thus, Warner Chilcott's avoided litigation costs are likely significantly lower than $6 million. But even using the $6 million figure, the no-AG payment here was nearly seven times Warner Chilcott's avoided litigation costs, and is plainly a large payment under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (explaining that defendants may be able to defend a reverse payment by showing that it "may amount to no more than a rough approximation of the litigation expenses saved through the settlement"); *id.* at 2237 (payment should be evaluated "in relation to the payor's anticipated future litigation costs").

131. Defendants likely studied and calculated the effects of generic competition for Loestrin 24, both on the brand's sales and the price of the drug, and the effect of the presence or absence of an authorized generic. The FTC Authorized Generic Study obtained data from numerous brand and generic drug companies (including Warner Chilcott and Watson) about the effects of authorized generics. It confirmed that, as a matter of standard business practice, both brand and generic companies calculate the financial effects of the presence or absence of an authorized generic. For brand name companies, the FTC Authorized Generic Study (p. 68) concluded:

> The brand-name firms' keen interest in the revenues arising from AGs and their intense concern with any impact of the AG on branded sales are reflected in their extensive forecasting and sales

> analysis documents. Virtually every brand-name company in the study that had marketed an AG produced multiple forecasts and revenue analyses in response to the FTC Special Orders. The forecasts were incorporated into different phases of company decision making, including decisions to market an AG, select an external distributor, determine launch timing, and project how much to manufacture. After launch of an AG, companies closely monitored actual revenues, price, and market share to facilitate adjustments based on market conditions.

132. Similarly, documents produced by the generic companies confirmed that they expected the introduction of an AG during the exclusivity period to substantially erode the expected profitability of the ANDA (pp. 81-82):

> In fact, various sales and pre-launch forecasts indicate that generic firms routinely assume the presence of an AG, and weave that consideration, along with assumptions about market size, substitution rates, price erosion, and the likely number of competitors, into their projections of sales and profitability of the ANDA-generic drug during the exclusivity period and beyond.

133. Discovery in this case is likely to reveal similar internal analyses by Defendants examining the financial effects of the presence or absence of an authorized generic version of Loestrin 24. Such internal analyses can then be used to further refine the quantification of the no-AG payment here.

134. Second, the Agreement obligated Warner Chilcott to pay Watson annual fees and a percentage of net sales above a specified baseline level in connection with Watson's co-promotion of Femring, a Warner Chilcott hormone therapy product, [redacted] Under the Femring co-promotion agreement, Watson performed a specified set of co-promotion services and received from Warner Chilcott [redacted]

[redacted] Femring's net annual sales were [redacted]. Using that figure, Watson could expect to receive payments of [redacted], plus an additional [redacted], or a total of [redacted] of the agreement. These payments were far in excess of Watson's cost of performance or the fair market value of that performance. The Femring co-promotion agreement was a way of compensating Watson for agreeing to delay the entry of its generic product.

135. Third, the Agreement gave Watson the exclusive right to earn highly profitable brand sales of a Warner Chilcott oral contraceptive that was in late-stage development at the time of the Agreement. Watson now markets that product under the brand name Generess Fe, a chewable oral contraceptive. The Generess Fe agreement gave Watson exclusive rights [redacted] The terms of this agreement were more favorable to Watson than a typical licensing agreement involving a drug under development. The Generess Fe agreement was expected to be, and has proven to be, highly profitable to Watson. From April 2011 to April 2015, when generic versions of the drug entered the market, Generess Fe generated total sales of more than $268 million and Watson earned profits of approximately [redacted] The Generess Fe agreement was a way of compensating Watson for agreeing to delay the entry of its generic product.

136. Fourth, in addition to agreeing not to launch its own authorized generic, Warner Chilcott agreed not to grant a license to any other manufacturer to enter with a generic version of Loestrin 24 until at least 180 days after Watson entered the market. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the only generic Loestrin 24 on the market, absent another generic manufacturer outlasting a 30-month stay or obtaining a court

order permitting such entry. By the time of the Agreement, however, Watson understood that it had forfeited its entitlement to 180-day exclusivity under Hatch-Waxman because as of October 17, 2008, Watson had failed to obtain tentative FDA approval to market generic Loestrin 24. Watson was aware that a first-filed ANDA that failed to receive tentative FDA approval within 30 months of first submitting its ANDA forfeited the 180 days of marketing exclusivity provided for under Hatch-Waxman. On September 1, 2009, the date the FDA issued its Final Approval of Watson's ANDA, the FDA's Approval Letter concluded that Watson forfeited its 180-days of exclusivity.

137. As the FDA explained in its Approval Letter: "FDA has determined that Watson was the first applicant to submit a substantially complete application that contained a Paragraph IV certification to the '394 Patent for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-day regimen), and therefore, was eligible for 180-day generic-drug exclusivity under section 505(j)(5)(B)(iv) of the Act. However, your eligibility for 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(IV). Your ANDA was received by the agency on April 17, 2006, and was never granted tentative approval. The ANDA filing date plus 30 months was October 17, 2008; therefore, this ANDA was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). We also have determined that the requirements for approval of this ANDA were not changed or reviewed after your ANDA was filed, nor was a related citizen petition submitted that would extend the 30-month period as described in section 505(q)(l)(G) of the Act. We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg and Ferrous Fumarate Tablets 75 mg (24-day regimen) was forfeited by Watson."

138. Thus, Watson was not entitled to first filer exclusivity under Hatch-Waxman. The private contractual substitute to which Warner Chilcott and Watson agreed had substantial value to Watson, again at the expense of Plaintiffs.

139. In a February 19, 2013 earnings call, Paul Bisaro, Watson's Chief Executive Officer, President and Director, represented that Watson retained 180-day exclusivity on Loestrin 24. Bisaro did not disclose, however, that this exclusivity was the product of Watson's agreement with Warner Chilcott rather than Hatch-Waxman. The September 1, 2009 FDA Approval Letter denying Watson's entitlement to exclusivity establishes that the 180-day exclusivity to which Bisaro referred was the result of its Reverse Payment Agreement with Warner Chilcott.

140. Warner Chilcott made these payments to Watson in exchange for Watson's agreement to delay generic competition to Loestrin 24 until January 2014 or the date on which another generic version of Loestrin 24 Fe entered the U.S. market. Absent Watson's agreement to delay generic Loestrin 24, Warner Chilcott would not have agreed to: (a) refrain from launching an authorized generic Loestrin 24 during Watson's first 180 days of marketing; (b) hire Watson as a co-promoter of Femring; (c) grant Watson an exclusive license to market and sell Generess Fe; (d) guarantee Watson 180 days of exclusivity, which it had otherwise forfeited, to market a generic version of Loestrin 24; and/or (e) accept the price and/or other terms that it did under those provisions of the Agreement. Absent Warner Chilcott's agreement to make these payments, Watson would not have agreed to delay entry for over four years. Warner Chilcott paid Watson to delay the market entry of generic Loestrin 24.

2. Lupin

141. Warner Chilcott made sure that the second ANDA-filer for Loestrin 24 Fe—Lupin—would not enter the market before Watson. Before the court reached the merits of

Lupin's invalidity and/or non-infringement arguments, Warner Chilcott paid Lupin to drop its patent challenge and stay out of the market until after Watson was permitted to enter the market under Watson's unlawful agreement with Warner Chilcott.

142. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott entered into a second Reverse Payment Agreement with Lupin, whereby Warner Chilcott agreed to pay Lupin substantial sums as a *quid pro quo* for Lupin's agreement to delay marketing its less expensive generic version of Loestrin 24 Fe until July 22, 2014, the month that the '394 Patent was set to expire. Pursuant to that Agreement, Warner Chilcott ended the '394 Patent litigation against Lupin, and Lupin dropped its counterclaims against Warner Chilcott.

143. Warner Chilcott would not have agreed to pay Lupin absent its agreement to delay its generic entry, and Lupin would not have agreed to delay its generic entry absent the payments. Warner Chilcott's payments to Lupin under the Agreement took at least two forms.

144. First, the agreement gave Lupin the right to purchase and sell in the United States an authorized generic version of Asacol 400 mg, a branded treatment for inflammatory bowel disease, to be supplied by Warner Chilcott, if a generic version of the Asacol 400 mg product were launched by another generic manufacturer in the United States. This agreement was more favorable to Lupin than typical authorized-generic distribution agreements. As of 2010, Asacol had annual sales of over $700 million. As detailed above, 80% of the brand sales can be expected to switch to generic sales within 6 months of generic launch, and an AG typically garners 50% of those generic sales. Both Warner Chilcott and Lupin expected Lupin to earn at least $100 million in annual profits pursuant to the Asacol authorized-generic agreement, more than any reasonable estimate of Warner Chilcott's avoided litigation expenses (for which Lupin

also received compensation separately). The Asacol authorized-generic agreement was a means of compensating Lupin for delaying entry.

145. Second, the agreement gave Lupin the right to purchase and sell in the United States an authorized generic version of Femcon Fe, another branded oral contraceptive manufactured by Warner Chilcott, to be supplied by Warner Chilcott, beginning on the earlier of (i) 180 days after the date that Teva Pharmaceutical Industries, Ltd (the "first-filer" with respect to Femcon Fe) entered the market with a generic equivalent to Femcon Fe, or (ii) January 1, 2013. This agreement was more favorable to Lupin than typical authorized-generic distribution agreements. Pursuant to the agreement, Lupin entered the market with generic Femcon Fe, which it marketed as Wymzya Fe, in October 2011, and since that time has made substantial sales of that product. But for this agreement, Lupin could not have begun making Femcon Fe sales until the end of the 30-month stay in February 2012, assuming that Lupin would have entered at risk at that time. Both Warner Chilcott and Lupin expected Lupin to earn at least $5 million in annual profits from the Femcon Fe agreement, more than any reasonable estimate of Warner Chilcott's avoided litigation expenses (for which Lupin also received compensation separately). The Femcon Fe authorized-generic agreement was a means of compensating Lupin for delaying entry.

146. Warner Chilcott made these payments in exchange for Lupin's agreement to delay generic competition to Loestrin 24 for more than two years (unless another generic entered first). Absent Lupin's agreement to delay generic Loestrin 24, Warner Chilcott would not have agreed to: (a) grant to Lupin the non-exclusive license to make or sell generic Femcon Fe; (b) grant to Lupin the license to make or sell, under certain circumstances, a generic version of Asacol 400 mg; and/or (c) grant the price and/or other terms that it did under those provisions of the

agreement. Absent these payments, Lupin would not have agreed to delay its entry. Warner Chilcott paid Lupin to delay the market entry of generic Loestrin 24.

147. Warner Chilcott paid Lupin to delay generic entry in order to both protect its Loestrin 24 monopoly and buy time to permit it to switch prescriptions to a follow-on branded version of Loestrin before generic Loestrin 24 became available.

3. Mylan

148. In July 2013, on the eve of trial, Warner Chilcott entered into a settlement and license agreement with Mylan Inc., Mylan Pharmaceuticals Inc., and Famy Care Ltd. to resolve the patent litigation related to Warner Chilcott's '394 Patent.

149. Pursuant to the agreement, Mylan and Famy Care agreed, among other things, not to commence marketing their generic equivalent Loestrin 24 product until the earlier of July 1, 2014 or the date on which a third party (other than pursuant to the January 2009 Watson settlement and license agreement) enters the market with a generic version of Loestrin 24 in the United States with or without authorization from Warner Chilcott. Pursuant to the agreement, Warner Chilcott's patent litigation against Mylan was dismissed.

E. Switch from Loestrin 24 to Minastrin 24

150. To exploit the market "disconnect" and preserve its supracompetitive sales and profits, Warner Chilcott sought to delay the entry of generic Loestrin 24 as long as possible, by, among other things, the rote filing of patent infringement cases regardless of their merit, and unlawful pay-offs to generic manufacturers.

151. Warner Chilcott used the delay that it obtained by filing sham patent cases and paying off generic competitors to implement an anticompetitive "product hop." It discontinued Loestrin 24 and introduced Minastrin 24, a drug with the same active ingredients, the same

amounts of active ingredient, the same doses and dosing regimen and the same indication as Loestrin 24. There are only two differences between Loestrin 24 and Minastrin 24. First, Warner Chilcott added spearmint and a sweetener to the inactive pills (only). Second, Warner Chilcott's proposed labeling referred to the dosage form as chewable and instructed women to chew and then swallow the pills. Warner Chilcott intended this product hop to protect as many Loestrin 24 sales as possible from generic competition.

152. There is no medical reason for women to ingest the inactive pills that are included when an oral contraceptive prescription is filled. Making the inactive pills more palatable conveys no medical benefit. In fact, the labeling for Loestrin 24 refers to the inactive pills as "reminder" pills. Thus, with respect to the pills that actually introduce the active ingredients into the human body and create the therapeutic (*i.e.*, contraceptive) effect, there is literally no physical difference between an active Loestrin 24 pill and an active Minastrin 24 pill.

153. Warner Chilcott may attempt to justify its product hop by noting that some individuals have trouble swallowing pills. But, as noted, Warner Chilcott made no changes at all to the active Loestrin 24 pills, which were already chewable before Minastrin 24 was introduced. Moreover, Loestrin 24, Minastrin 24 and most other oral contraceptives are only 6mm in diameter—among the smallest oral medications in existence. Complaints about swallowing are typically associated with small children and the elderly—two patient populations who do not take oral contraceptives. In fact, studies show that adult patients prefer coated tablets to chewable tablets by a large margin.

154. It was essential to Warner Chilcott to launch and convert as many Loestrin 24 prescriptions as possible to Minastrin 24 before generic versions of Loestrin 24 were available in the market. Beating generics to the market would allow Warner Chilcott to effect the switch at a

time when no competing manufacturer had the incentive or ability to counter Warner Chilcott's marketing message to doctors.

155. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market.

156. Minastrin 24 offers no medical, convenience, or other benefits to consumers, as compared to Loestrin 24. Consequently, Warner Chilcott's product hop depended on launching Minastrin 24 before generic versions of Loestrin 24 became available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the FDA approved Minastrin 24. Thus, Warner Chilcott would not have launched Minastrin 24 or, if it had, it would have made few sales.

157. Warner Chilcott first submitted its NDA for Minastrin on May 20, 2008. On January 12, 2009, Warner Chilcott withdrew its request for FDA approval, citing "business reasons." The "business reason" for the withdrawal was that three days earlier, on January 9, 2012, Warner Chilcott had entered into its Reverse-Payment Agreement with Watson, purchasing a delay in generic competition until January 2014. Since the sole purpose of reformulating Loestrin 24 was to impair generic competition, this delay in generic competition temporarily alleviated Warner Chilcott's need to reformulate the product.

158. Warner Chilcott then re-submitted the same NDA on September 12, 2010 and withdrew it a second time on November 15, 2010—a month after it bought Lupin's agreement to delay marketing its generic version of Loestrin 24 until July 2014. Again, having purchased a

delay in generic competition, Warner Chilcott no longer had an immediate need to reformulate the product.

159. Warner Chilcott re-submitted the NDA a third time on July 9, 2012 and pursued it to completion only when the delays that Warner Chilcott bought from Watson and Lupin were finally coming to an end. Warner Chilcott obtained FDA approval in May 2013 and implemented the product hop beginning in August 2013, converting the market to Minastrin 24 before the entry of generic Loestrin 24 in January 2014.

160. The discontinuation of Loestrin 24 and the launch of Minastrin 24 were intended to limit the number of Loestrin 24 prescriptions that would be subject to AB-rated generic competition when a generic version of Loestrin 24 finally became available. In this regard, the product hop was enormously successful. By the time Watson launched its generic version of Loestrin 24 in January 2014, there were virtually no prescriptions being written for Loestrin 24 and thus no market for Watson's generic. Absent the unlawful reverse-payment agreements with Watson and Lupin, Warner Chilcott would not have been able to implement the product hop prior to the launch of generic Loestrin 24.

VI. ANTICOMPETITIVE EFFECTS OF DEFENDANTS' SCHEME

161. Warner Chilcott's scheme and payments to suppress generic competition have delayed and substantially diminished the sale of generic Loestrin 24. By first delaying the onset of generic competition and then drastically reducing the prescription base, Defendants deprived purchasers of low cost generic Loestrin 24.

162. Warner Chilcott's overarching anticompetitive scheme, and the Generic Defendants' participation in it, delayed and substantially diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated prices. But for Defendants' illegal conduct, generic manufacturers would have been able

to enter the market unimpeded and compete on the merits against Loestrin 24. Generic competitors would also have been able to compete as early as September 2009, and additional generic competitors would have entered the market thereafter. Defendants' conduct unlawfully prevented purchasers of Loestrin 24 from obtaining the benefits of unimpaired generic competition.

163. Defendants' scheme and unlawful payments harmed Plaintiffs. The anticompetitive scheme and payments enabled Defendants to: (a) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24; and (c) allocate 100% of the U.S. market for Loestrin 24 and its generic equivalents to Warner Chilcott.

164. But for the anticompetitive scheme: (i) Watson would have begun selling AB-rated generic versions of Loestrin 24 on or shortly after receiving final FDA approval of its generic Loestrin 24 ANDA on September 1, 2009; (ii) an increasingly competitive market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets would have emerged; and (iii) Warner Chilcott would not have developed or marketed Minastrin 24 and switched a substantial portion of Loestrin's sales to that product, or generic Loestrin 24 would have entered the market before Minastrin 24 was launched, and Warner Chilcott would have been able to switch no or few prescriptions to it.

165. Defendants' unlawful conduct delayed and diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Loestrin 24 would have occurred earlier, because, at a minimum, Watson would have launched its generic version of Loestrin 24 before January 2014 and Warner Chilcott or its designee would have entered the market with an authorized generic version of Loestrin 24.

166. As a consequence, Plaintiffs and their assignors sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

167. Defendants' unlawful scheme continues to impose economic loss and damage on Plaintiffs notwithstanding the belated entry of generic Loestrin in January 2014. The generic competition that began in January 2014 did not instantaneously transform the market into the market that would have existed if generic competition had begun in September 2009. Moreover, the continuing harm caused by Defendants' scheme has been exacerbated by Warner Chilcott's product-hopping strategy. As detailed above, Warner Chilcott's product-hopping strategy ensured that, by the time generic versions of Loestrin 24 became available, most of the prescriptions that would have been filled with generic Loestrin 24 had been switched to Minastrin 24, thereby drastically reducing the benefits of generic entry. If generic competition had begun in September 2009, Warner Chilcott's product-hopping strategy would not have occurred or, at the very least, would have been far less successful. For these reasons, Defendants' unlawful conduct threatens continuing loss and damage to Plaintiffs unless restrained and enjoined by this Court.

VII. INTERSTATE COMMERCE

168. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VIII. MARKET POWER AND MARKET DEFINITION

169. At all relevant times, Warner Chilcott had market power with respect to Loestrin 24 because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales.

170. A small but significant, non-transitory price increase above the competitive level for Loestrin 24 by Warner Chilcott would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

171. At competitive price levels, Loestrin 24 does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Loestrin 24.

172. Some formulations of oral contraceptives have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles. The differing efficacy, safety and side effect profiles of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient. The FDA does not consider these products bioequivalent, and there is variation in the dosage of the active ingredients.

173. Even though physicians may choose from a number of different oral contraceptive pills when initially making a prescription, and in theory may switch a patient from one oral contraceptive to another, once the physician and patient find one that is well-tolerated, it is unlikely that the patient will switch to a different oral contraceptive based on variations of price of 10% or less. Doctors generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price.

174. For clinical reasons, among others, physicians and patients preferred 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets to other products designed to prevent pregnancy. Due to, among other reasons, its use and varying ability to prevent pregnancy while causing shorter, lighter periods, the product consisting of 24

norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets in the United States is significantly differentiated from all other products.

175. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24. At all relevant times, Warner Chilcott's price for Loestrin 24 has been substantially above its marginal cost of production, and substantially above its marginal cost including marketing costs. Warner Chilcott has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives).

176. Warner Chilcott needed to control only Loestrin 24 and its AB-rated generic equivalents, and no other products, in order to maintain the price of Loestrin 24 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 would render Warner Chilcott unable to profitably maintain supracompetitive prices for Loestrin 24.

177. Warner Chilcott knew that entry of a generic version of Loestrin 24 would be a uniquely significant market event. The entry of other branded oral contraceptives (or generic versions of those other brands) did not take substantial sales from Loestrin 24 or cause Warner Chilcott to lower its price. But Warner Chilcott predicted that entry of generic Loestrin 24 would immediately cause branded Loestrin 24 to lose well more than half of its unit sales. Likewise, Watson estimated that its generic version of Loestrin 24 would take essentially all of its sales from branded Loestrin 24 and few if any sales from other branded oral contraceptives (or generic versions of those other brands). Lupin predicted the same with respect to its generic version of Loestrin 24.

178. Warner Chilcott, Watson, and Lupin predicted that the competitive impact of a generic version on branded Loestrin 24 would be substantial. Among other things, all three

Defendants predicted that entry of generic Loestrin 24 would deliver hundreds of millions of dollars of savings to drug purchasers.

179. Warner Chilcott sold Loestrin 24 at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

180. Warner Chilcott had, and exercised, the power to exclude and restrict competition in the market for Loestrin 24 and its AB-rated generic equivalents.

181. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

182. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is Loestrin 24 and its AB-rated generic equivalents. During the relevant time, Warner Chilcott has been able to profitably maintain the price of Loestrin 24 well above competitive levels.

183. The relevant geographic market is the United States and its territories.

184. Until January 2014, Warner Chilcott's market share in the relevant market was 100%, implying a substantial amount of market power.

IX. EFFECT ON COMPETITION AND INJURY TO PLAINTIFFS

185. But for the anticompetitive conduct alleged above, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, the date its ANDA 78-267 received final FDA approval. Warner Chilcott would have launched an authorized generic version of Loestrin 24 at that same time. Lupin and other generic manufacturers would have entered the market with additional generic version of Loestrin 24 thereafter.

186. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Loestrin 24 from generic competition.

187. Watson, Lupin, and Mylan have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

188. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Loestrin 24, has caused Plaintiffs and/or their assignors to pay more than they would have paid for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets absent Defendants' illegal conduct.

189. But for Defendants' anticompetitive conduct, Plaintiffs and/or their assignors would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets by: (a) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin; and (b) purchasing generic Loestrin 24 at lower prices sooner.

190. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Loestrin 24, and/or (b) challenging the validity or infringement of the '394 Patent in court.

191. Plaintiffs and/or their assignors purchased substantial amounts of Loestrin 24. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for oral contraceptives comprising 24

norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets. Plaintiffs and/or their assignors paid prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Plaintiffs and/or their assignors were deprived of the opportunity to purchase lower-priced generic Loestrin 24 instead of expensive brand Loestrin 24; and (2) Plaintiffs and/or their assignors paid artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets.

192. As a consequence, Plaintiffs and/or their assignors have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. Plaintiffs' and/or their assignors' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

193. Thus, Defendants' unlawful conduct deprived Plaintiffs and/or their assignors of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT

194. Defendants' anticompetitive conduct enabled them to directly charge Plaintiffs and/or their assignors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

195. The prices paid by Plaintiffs and/or their assignors were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

196. Plaintiffs will continue to suffer loss and injury as a result of Defendants' anticompetitive scheme unless Defendants are enjoined by this Court.

XI. CLAIMS FOR RELIEF

Claim I: Violation of 15 U.S.C. § 2
Monopolization (Overall Scheme)
(Asserted Against Warner Chilcott)

197. Plaintiffs repeat and incorporate by reference paragraphs 1 through 196 above as though fully set forth herein.

198. At all relevant times, Warner Chilcott possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

199. Through its overarching anticompetitive scheme, as alleged above, Warner Chilcott willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of superior product, business acumen, or historic accident, and thereby injured Plaintiffs. Warner Chilcott's unlawful conduct included:

a. enforcing the '394 Patent, which it knew to have been obtained by a knowing fraud on the PTO;

b. improperly listing the '394 Patent in the Orange Book;

c. improperly filing and prosecuting sham patent infringement actions against companies seeking to market competing versions of Loestrin 24;

d. entering into unlawful Reverse Payment Agreements with its generic competitors Watson and Lupin; and

e. during the delay it purchased from Watson and Lupin, switching the market to Minastrin 24 to prevent automatic generic substitution when generic versions of Loestrin 24 finally became available.

Warner Chilcott's scheme was designed to delay the introduction of generic formulations of Loestrin 24 into the market.

200. It was Warner Chilcott's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

201. Warner Chilcott's scheme substantially harmed competition.

202. There is and was no cognizable, nonpretextual procompetitive justification for Warner Chilcott's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Warner Chilcott were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

203. As a direct and proximate result of Warner Chilcott's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors suffered injury to their business and property.

Claim II: Violation of 15 U.S.C. § 2
Attempt to Monopolize
(Asserted Against Warner Chilcott)

204. Plaintiffs repeat and incorporate by reference paragraphs 1 through 196 above as though fully set forth herein.

205. Warner Chilcott, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Warner Chilcott's conscious objective to control prices and/or to exclude competition in the relevant market.

206. The natural and probable consequence of Warner Chilcott's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

207. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Warner Chilcott will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

208. As a direct and proximate result of Warner Chilcott's illegal and monopolistic conduct, Plaintiffs and/or their assignors suffered injury to their business and property.

Claim III: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against Warner Chilcott and Watson)

209. Plaintiffs repeat and incorporate by reference paragraphs 1 through 196 above as though fully set forth herein.

210. The Reverse Payment Agreement between Warner Chilcott and Watson involves: (a) a substantial payment from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 until January 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic version of Loestrin 24 for over four years. Absent the payments, Watson would not have agreed to delay marketing its generic version of Loestrin 24 until January 22, 2014. In addition, the Watson Reverse Payment Agreement is a *per se* unlawful horizontal market allocation agreement that divides the relevant market temporally rather than geographically.

211. The purpose and effect of the unlawful Watson Reverse Payment Agreement was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price which Plaintiffs and/or their assignors would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

212. The Watson Reverse Payment Agreement covers a sufficiently substantial percentage of the relevant market to harm competition.

213. The Watson Reverse Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Watson Reverse Payment Agreement is a horizontal market allocation and price

fixing agreement between actual or potential competitors as well as a reverse-payment agreement. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the Watson Reverse Payment Agreement is to delay generic competition to Loestrin 24 and there is and was no legitimate, nonpretextual, procompetitive business justification for the payment that outweighs is harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

214. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

215. The goal, purpose and/or effect of the Watson Reverse Payment Agreement was to prevent and/or delay generic competition to Loestrin 24 and enable Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 without a substantial loss of sales. By means of Warner Chilcott's payment to Watson, both Defendants shared the supracompetitive profits that their unlawful agreement made possible.

216. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and/or their assignors suffered injury to their business and property.

Claim IV: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against Warner Chilcott and Lupin)

217. Plaintiffs repeat and incorporate by reference paragraphs 1 through 196 above as though fully set forth herein.

218. The Reverse Payment Agreement between Warner Chilcott and Lupin involves: (a) a substantial payment from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 until July 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Lupin under the Lupin Reverse Payment Agreement were the

quid pro quo for Lupin's agreement to delay marketing its generic version of Loestrin 24 Fe for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic version of Loestrin 24 until July 22, 2014.

219. The purpose and effect of the unlawful Lupin Reverse Payment Agreement was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price Plaintiffs and/or their assignors would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20µg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

220. The Lupin Reverse Payment Agreement covers a sufficiently substantial percentage of the relevant market to harm competition.

221. The Lupin Reverse Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Agreement was to delay generic competition to Loestrin 24 and there is and was no legitimate, nonpretextual, procompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

222. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

223. The goal, purpose and/or effect of the Lupin Reverse Payment Agreement is to prevent and/or delay generic competition to Loestrin 24 and enable Warner Chilcott to continue

charging supracompetitive prices for Loestrin 24 without a substantial loss of sales. By means of Warner Chilcott's payment to Lupin, both Defendants shared the supracompetitive profits that their unlawful agreement made possible.

224. As a direct and proximate result of Defendants' unlawful restraint of trade Plaintiffs and/or their assignors suffered injury to their business and property.

Claim V: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against All Defendants)

225. Plaintiffs repeat and incorporate by reference paragraphs 1 through 196 above as though fully set forth herein.

226. As alleged above, Warner Chilcott, Watson and Lupin entered into and engaged in an overarching anticompetitive conspiracy and scheme to block and delay market entry of AB-rated generic versions of Loestrin 24. The unlawful agreements between Warner Chilcott and the Generic Defendants allocated all sales of Loestrin 24 and its AB-rated generic equivalents in the United States to Warner Chilcott; delayed the sales of generic Loestrin 24 products; and fixed the price Plaintiffs and/or their assignors would pay for Loestrin 24 and its AB-rated generic equivalents at the higher, branded price.

227. The goal, purpose and/or effect of the conspiracy was to restrain competition in the United States market for Loestrin 24 products in violation of Sherman Act Section 1, 15 U.S.C. § 1. The conspiracy prevented and/or delayed generic competition to Loestrin 24 and enabled Warner Chilcott to continue earning monopoly profits on its sales of Loestrin 24, which it agreed to share with Watson and subsequently with Lupin. Defendants' conspiracy had substantial and prolonged adverse effects on competition in the United States market for Loestrin 24 products.

228. The conspiracy also enabled Warner Chilcott to switch prescriptions from Loestrin 24 to Minastrin 24. In the absence of the conspiracy (and agreement from the Generic Defendants to stay off the market), Warner Chilcott would not have developed or marketed Minastrin 24 and, even if it had, generic Loestrin 24 would have entered the market before that product was launched, thereby impeding Warner Chilcott from switching prescriptions to Minastrin 24 and protecting those prescriptions from AB-rated generic competition.

229. As a direct and proximate result of the Defendants' concerted conduct, as alleged herein, Plaintiffs and/or their assignors suffered injury to their business and property.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XIII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Respectfully submitted,

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